



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

HM12/0615

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APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP/ART UNIT	DATE MAILED
09/393,743	09/10/99	016	CHOI, F	1616 06/15/01
First Named Applicant	DUPONCHELLE,	35 USC 154(b) term ext. = 0 Days.		

TITLE OF INVENTION BICARBONATE-BASED SOLUTION IN TWO PARTS FOR PERITONEAL DIALYSIS OR SUBSTITUTION IN CONTINUOUS RENAL REPLACEMENT THERAPY

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1 DI-5417	424-717.000	H70	UTILITY	NO	\$1240.00	09/17/01

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
- B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give application number and batch number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PATENT AND TRADEMARK OFFICE COPY

Notice of Allowability

Application No.

09/393,743

Examiner

Frank I Choi

Applicant(s)

DUPONCHELLE ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Amendment (5/16/01), IDS (5/16/01).
2. ☒ The allowed claim(s) is/are 1-6, 21-30[renumbered as claims 7-16].
3. ☐ The drawings filed on _____ are acceptable as formal drawings.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE FOR SUBMITTING NEW FORMAL DRAWINGS, OR A SUBSTITUTE OATH OR DECLARATION.** This three-month period for complying with the REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL is extendable under 37 CFR 1.136(a).

6. ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
7. ☒ Applicant MUST submit NEW FORMAL DRAWINGS
 - (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review(PTO-948) attached
 - 1) ☐ hereto or 2) ☒ to Paper No. 4.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

8. ☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any reply to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE / SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

Attachment(s)

- | | |
|---|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. <u>11</u> . |
| 5 <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. <u>10</u> . | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other |

EXAMINER'S AMENDMENT/REASONS FOR ALLOWANCE

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Robert Barrett on 5/22/01.

The application has been amended as follows:

Claim 21, lines 1,2: delete the entire phrase “, each part being separately stored from the other part until use, the solution” from lines 1,2 of Claim 21.

Claim 21, line 7: after “7.6” but before the period mark insert the following:

C1 -- ; wherein the first part and the second part are separately stored from each other until use --.

Examiner notes that the above amendment is solely for the purposes of clarifying claim language is not intended to change the scope of any patent protection provided therein. Further, it is noted that After-Final Amendment (5/16/01) has been entered.

The following is an examiner's statement of reasons for allowance: The present invention as amended is directed to a two-part bicarbonate containing solution comprising a first part housed in a first container including an alkaline bicarbonate concentrate having a pH from 8.6 to 10.0, and a second part housed in a second container including an acidic concentrate having a pH from about 1.0 to 3, the pH of the acidic concentrate effective to obtain, when the two parts are mixed, a solution having a pH of 6.5 to 7.6; a two-part bicarbonate containing solution

comprising a first part including an alkaline bicarbonate concentrate having a pH from 9 to 10.0, and a second part including an acidic concentrate having a pH from about 1.3 to 2.5, the pH of the acidic concentrate effective to obtain, when the two parts are mixed, a solution having a pH of 6.5 to 7.6, wherein the two parts are stored separately from each other until use; a two-part bicarbonate containing solution comprising a first part housed in a first container including an alkaline bicarbonate concentrate having a pH from about 9 to 10.0, and a second part housed in a second container including an acidic concentrate having a pH from about 1.0 to 3, wherein the mixed solution contains the claimed amounts of bicarbonate, calcium, sodium, magnesium, potassium, chloride, lactate and acetate.

In consideration of Amendment (5/16/01) and in reconsideration of the prior Office Action and response thereto, the claimed invention, as amended, is not expressly disclosed by the prior art. Further, the formulating the bicarbonate solution at the claimed pH range unexpectedly results in a two-part dialysis solution which does not require the addition of carbon dioxide or the use of a gas barrier to stabilize the bicarbonate solution (See Amendment (5/16/01), pgs. 3-5, Amendment (12/18/00), pgs. 5-8). As such, the claimed invention, as amended, is deemed allowable over the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Conclusion


A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628.

FIC

5/31/2001


JOSE G. DEES
SUPERVISORY PATENT EXAMINER
1616

